1.0 PURPOSE

The purpose of this policy is to identify and apply consistent training requirements for Good Clinical Practice (GCP) and Human Subjects Protection (HSP) at Division of AIDS (DAIDS) supported clinical research sites.

2.0 SCOPE

This policy represents DAIDS minimal acceptable requirements for GCP and HSP training, for clinical research site staff engaged in the conduct of all DAIDS funded and/or sponsored clinical trials. Adherence to this policy will fulfill the National Institutes of Health (NIH) requirements for human subjects protection training.

- All individuals named on the Form FDA 1572 or DAIDS Investigator Agreement and any site personnel who have more than minimal contact with study subjects or confidential study data, records, or specimens are required to receive GCP and HSP training as described later in the policy section.

- All other personnel (e.g., drivers, couriers. clerical and administrative staff etc.) with minimal involvement in the conduct of the research or contact with the participants, should receive appropriate training emphasizing the protection of participant privacy and confidentiality.

3.0 BACKGROUND

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well being of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. All clinical trials funded by the DAIDS shall comply with ICH GCP guidelines.

It is an NIH policy that all key personnel defined as Individuals who will be involved in the design and conduct of NIH-funded human subjects clinical research must receive education on the protection of human research participants before funds are awarded. Individuals who become involved in the project after the initial award must also receive training.

4.0 DEFINITIONS

See DAIDS Glossary.

5.0 RESPONSIBILITIES

The grant or contract PI is responsible for ensuring that all personnel receive the appropriate Good Clinical Practice and Human Subjects Protection training. The PI is also responsible for ensuring that new staff (added after the initial award) receive training in the principles of good clinical practice and human subject protections during orientation and that new personnel are adequately supervised during the period prior to formal GCP and HSP training.

6.0 POLICY

- The initial GCP and HSP training received by each person must represent a comprehensive overview of the GCP and HSP guidelines and should also include other applicable regulations. Typically an 8-16 hour course will satisfy this requirement. A comprehensive GCP course will include:
    - International Conference on Harmonisation, Guideline for Good Clinical Practice E6
    - U.S. Code of Federal Regulations 45 CFR 46 Protection of Human Subjects - required for all NIH-funded clinical research
        - Subpart A Basic HHS Policy for Protection of Human Subjects
        - Subpart B Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
        - Subpart C Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as subjects
        - Subpart D Additional Protections for Children Involved as Subjects in Research

- The Belmont Report
- The Declaration of Helsinki
- The Nuremberg Code
- Roles and responsibilities of investigators, IRBs, and sponsors
- Informed consent process
- Adequate and complete source documentation
- Local regulations as appropriate

For clinical trials intended to be submitted to U.S. regulatory authorities:

- 21 CFR Part 312 Investigational New Drug Application
- 21 CFR Part 50 Protection of Human Subjects
- 21 CFR Part 11 Electronic Records and Signature

- Site personnel must obtain GCP and HSP training prior to the initiation (that is, before screening or enrollment of the first subject) of a DAIDS-funded study/trial, and on a recurring basis as specified by this policy.

- The Site PI will maintain complete training records and make them available to DAIDS staff, study monitors, or others as designated during site visits. Documentation of training shall consist of a listing of: trainee name(s), date of training, title of course, and number of course hours. The training agenda and name of the trainer must be attached.

- The Site PI will provide documentation of the training to the Program Officer and/or other designated DAIDS staff upon request.

- New site personnel (hired after trial initiation) shall receive formal HSP and GCP training within 90 days of assignment to, and prior to their functioning without direct supervision and on a recurring basis as specified by this policy. Proof of training for new personnel will be maintained onsite as soon as the documentation is received and

forwarded to the Program Officer as part of the Annual Report. HSP and GCP training provided by a site staff member who has successfully completed DAIDS sponsored workshops and used DAIDS approved training materials will meet the necessary requirements for initial training of new staff and ongoing refresher training.

- It is required that Site PIs and designated site personnel take a "refresher" course on HSP and GCP. At a minimum, an interval of every three years is recommended.

7.0 REFERENCES

The below online information is current as of the Effective Date of this policy.

U.S. Code of Federal Regulations, Title 45, Part 46 and Subparts
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice
http://www.fda.gov/cder/guidance/959fnl.pdf

U.S. Code of Federal Regulations, Title 21, Parts 11, 50, 56, 312, 314
http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200521

The Belmont Report
http://www.fda.gov/oc/ohrt/irbs/belmont.html

NIH Required Education in the Protection of Human Research Participants Policy
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

Office for Human Research Protections
http://www.hhs.gov/ohrp/

The Declaration of Helsinki
http://www.wma.net/e/policy/b3.htm

The Nuremberg Code
http://www1.ushmm.org/research/doctors/codeptx.htm

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at:

NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm

The signed original is maintained in the OPCRO policy office.

10.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement
1.0	14 JUL 06	N/A	N/A	N/A

11.0 APPENDICES

None.

12.0 APPROVAL

	Signature	Program/Branch	Date
Authorized By:	Richard Hafner Richard Hafner, MD Director	Office for Policy in Clinical Research Operations	July 14, 2006